REMARKS

Rejection under § 101

The claimed polypeptides can be used as markers for angiogenesis. This utility is clearly described throughout the specification, e.g., on Page 1, lines 15-16 ("The polynucleotides are expressed in angiogenesis and are therefore useful in variety of ways, including, but not limited to, as molecular markers for blood vessels and blood vessel formation") and Page 34, beginning on line 10. The importance of angiogenesis in a number of different diseases and conditions is disclosed in the specification. See, e.g., Page 1, line 26-Page 2, line 18. Particular diseases associated with abnormal angiogenesis are also specifically identified. See, e.g., Page 32, lines 25-29.

The specification describes the clinical use of these polypeptides for assessing vascularization in cancer biopsy samples. On Page 34, it stated:

> The present invention also relates to detecting the presence and/or extent of blood vessels in a sample. The detected blood vessels can be established or pre-existing vessels, newly formed vessels, vessels in the process of forming, or combinations thereof. A blood vessel includes any biological structure that conducts blood, including arteries, veins, capillaries, microvessels, vessel lumen, endothelial-lined sinuses, etc. These methods are useful for a variety of purposes. In cancer, for instance, the extent of vascularization can be an important factor in determining the clinical behavior of neoplastic cells. See, e.g., Weidner et al., *N. Engl. J. Med.*, 324:1-8, 1991. Thus, the presence and extent of blood vessels, including the angiogenic process itself, can be useful for the diagnosis, prognosis, treatment, etc., of cancer and other neoplasms. Detection of vessels can also be utilized for the diagnosis, prognosis, treatment, of any diseases or conditions associated with vessel growth and production, to assess agents which modulate angiogenesis, to assess angiogenic gene therapy, etc.

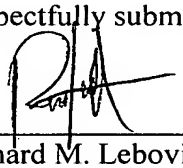
Rejection under §102

To anticipate, a reference must disclose and enable each element of the claimed invention. WO98/25962 does not disclose a polypeptide, e.g., which comprises the sequence CDLFIQ, and therefore can not anticipate the claimed invention. Compare Claim 8.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Richard M. Lebovitz, Reg. No. 37,067
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: ORIGEN-0011

Date: August 3, 2004

This utility in angiogenesis is adequate to satisfy the requirements of 35 U.S.C. § 101.

Tissue-specificity was published by the Patent Office as sufficient to meet the statutory requirements to get a patent. Example 12 of the *Revised Interim Utility Guidelines Training Materials* is of a marker that is specific for a cancer – which is a type of tissue specificity. There is no reason why tissue specificity of normal tissue (e.g., for blood vessels) would not analogously satisfy the utility requirements, especially when it is utilized in the context of cancer. Moreover, Example 6 of the *Synopsis of Application of Written Description Guidelines* provides an example of a claim to a polypeptide that is useful because of its tissue specificity, as a marker for normal glial tissues, i.e., "glial specific G-coupled protein receptor". See, Pages 28-29 of the Guidelines.

The attached declaration by Dr. Zairen Sun shows the expression pattern of several genes expressed during angiogenesis. According to Paragraph No. 8 of his declaration, ANH401 – described in the present application – is highly expressed during angiogenesis. It is expressed at very low levels immediately prior to the onset of angiogenesis, and then increases dramatically at one-hour and continues to be expressed throughout. He concludes that this expression pattern makes it useful as a marker for the onset of angiogenesis, as well as for the presence or absence of blood vessels in a tumor biopsy sample.

Since this utility is adequate, it is not necessary to establish that ANH401 possesses dehydrogenase activity. Therefore, although Applicant does not agree the examiner's characterization of the issue, at this juncture Applicant chooses not to provide any additional evidence of enzyme activity or to show the errors in the Office action rejecting this utility. However, Applicant does not acquiescence to the rejection, and reserves the future right to present evidence/arguments to the contrary.